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|---|-------------|----------------------|---------------------|------------------|--|
| 10/617,452 | 07/11/2003 | Shelley D. Minteer | SLU 4554.1 4859 | | |
| 321 7590 09/25/2007 SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102 | | | EXAMINER | | |
| | | | MARTIN, ANGELA J | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| N.F. | | Application No. | Applicant(s) | | |
|---|--|---|---|--|--|
| | | 10/617,452 | MINTEER ET AL. | | |
| | Office Action Summary | Examiner | Art Unit | | |
| | • | Angela J. Martin | 1745 | | |
| Period fo | The MAILING DATE of this communication app r Reply | ears on the cover sheet with the c | orrespondence address | | |
| WHIC - Exter after: - If NO - Failur Any n | DRTENED STATUTORY PERIOD FOR REPLY HEVER IS LONGER, FROM THE MAILING DA sions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. period for reply is specified above, the maximum statutory period we to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing of patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE | l. ely filed the mailing date of this communication. 0 (35 U.S.C. § 133). | | |
| Status | . • | | | | |
| 2a)⊠ | Responsive to communication(s) filed on <u>28 Ju</u> This action is FINAL . 2b) This Since this application is in condition for allowan closed in accordance with the practice under E | action is non-final. | | | |
| Dispositi | on of Claims | | | | |
| 5)□ 6)⊠ 7)□ | Claim(s) <u>1-77 and 113-140</u> is/are pending in the 4a) Of the above claim(s) <u>1-5, 7, 9, 11,27-36-41</u> Claim(s) is/are allowed. Claim(s) <u>6,8,10,12-26,42-44,46 and 47</u> is/are reClaim(s) is/are objected to. Claim(s) are subject to restriction and/or | <u>, 45,48-77 and 113-140</u> is/are wi | thdrawn from consideration. | | |
| Application | on Papers | • | | | |
| 10) | The specification is objected to by the Examiner The drawing(s) filed on is/are: a) acce Applicant may not request that any objection to the o Replacement drawing sheet(s) including the correction The oath or declaration is objected to by the Examiner | epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj | 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d). | | |
| Priority u | nder 35 U.S.C. § 119 | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| Attachment | (e) | | d | | |
| 1) Notice 2) Notice 3) Inform | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date 6/29/07. | 4) Interview Summary (Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other: | te | | |

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DETAILED ACTION

This Office Action is responsive to the Amendment filed on June 28, 2007. The Applicant amended claims 1, 2, 5, and 6. However, the rejection is made final for the following reasons of record.

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 6, 12-18, 23, 25, 42-44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gregg et al., U.S. Pat. No. 5,264,105.

Gregg et al., teach a bioanode comprising (a) an electron conductor;(b) at least one enzyme capable of reacting with an oxidized form of an electron mediator and a fuel fluid to produce an oxidized form of the fuel fluid and a reduced form of the electron mediator, the reduced form of the electron mediator being capable of releasing electrons to the electron conductor; and (c) an enzyme immobilization material comprising the electron mediator, the enzyme immobilization material being capable of immobilizing and stabilizing the enzyme, the material being permeable to the fuel fluid (claim 1; col. 6, lines 39-67). It teaches the enzyme immobilization material comprises modified perfluoro sulfonic acid-PTFE copolymer (Example 6; claim 7). It teaches a carbon-based material, metal oxide (col. 3, lines 13-16). It teaches graphite (col. 3, lines 13-16). It teaches pyridium cation (col. 3, lines 40-64). It teaches enzyme comprises an oxidoreductase (redox enzyme) (abstract). It teaches the enzyme comprises glucose oxidase (col. 3, lines 28-29). It teaches the enzyme immobilization material comprises perfluoro sulfonic acid-PTFE copolymer (Example 6).

Thus, the claims are anticipated.

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However, if the claims are not anticipated, in the alternative, the claims are obvious because although the prior art of record does not recite "the stabilized enzyme retaining at least about 75% of its initial catalytic activity for at least about 30 days", these properties would be inherent characteristics of the enzyme.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 7. Claims 6, 13-16, 24, 26 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yamamoto et al., U.S. Pat. Application Pub. 2002/0127440 A1.

Yamamoto et al., teach a bioanode comprising (a) an electron conductor (0031);(b) at least one enzyme (0029) capable of reacting with an oxidized form of an electron mediator and a fuel fluid to produce an oxidized form of the fuel fluid and a reduced form of the electron mediator, the reduced form of the electron mediator being capable of releasing electrons to the electron conductor; and (c) an enzyme immobilization material comprising the electron mediator, the enzyme immobilization

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material being capable of immobilizing and stabilizing the enzyme, the material being permeable to the fuel fluid (0032). It teaches the electron conductor is a carbon-based material (0031). It teaches the electron conductor is carbon paper (0031). It teaches the enzyme comprises a dehydrogenase (aldehyde dehydrogenase) (0034-first reaction catalyzed by dehydrogenase).

Thus, the claims are anticipated.

However, if the claims are not anticipated, in the alternative, the claims are obvious because although the prior art of record does not recite "the stabilized enzyme retaining at least about 75% of its initial catalytic activity for at least about 30 days", these properties would be inherent characteristics of the enzyme.

Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. Claims 8, 10, 19-22, 46, 47are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregg et al., U.S. Pat. No. 5,264,105, in view of Saini et al., U.S. Pat. No. 5,521,101.

Gregg et al., teach a bioanode as described above.

Saini et al., disclose an electrode comprising an electron mediator comprising potassium ferrocyanide (col. 6, lines 34-37). Saini discloses that the polymeric material is Nafion (perfluoro sulfonic acid-PTFE copolymer) (col. 11, lines 5-60). It teaches a quarternary ammonium cation wherein R1-R4 are butyl or ethyl (claim 17). It teaches electron conductor comprises modified perfluorosulfonic acid-PTFE (Nafion) copolymer (micelle) (col. 12, lines 15-23; Example 2).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Gregg's Nafion with tertbutyl ammonium ion and enzyme-Nation compositions, as taught by Saini, for the benefit of eliminating acid groups and increasing the robustness of the immobilizing material. Saini disclose that it is known to use the foregoing materials or components in fuel cell applications regardless of the specific type of fuel cells.

Response to Arguments

10. Applicant's arguments filed 6/28/07 have been fully considered but they are not persuasive. Applicant argues "Gregg et al. generally disclose enzyme electrodes that contain a three-dimensional redox polymer network that has bound redox enzymes for use in amperometric biosensors. Although Gregg et al. describe enzymes that are immobilized within redox polymers, the reference is silent on the stability of these enzymes within the electrodes." However, the stability of these enzymes in the electrodes would be an inherent characteristic. Applicant further argues, "applicants

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provide the following evidence that the enzyme stability is not necessarily present in the cited references. Applicants refer to a later publication by one of the same inventors of the Gregg et al. electrode (Adam Heller of the University of Texas, Austin; referenced as Ohara et al.)." However, the Ohara et al., reference is not equivalent to the Gregg et al., reference with respect to the electrodes. As recited by the Applicant, "electrodes described by Ohara et al. are similar to the electrodes described by Gregg et al. and differ primarily in the ligands attached to the Os center of the redox polymer." However, the Examiner would not be able to determine how the differing ligands in Gregg et al., and Ohara et al., would affect the stability and overall characteristics of the electrodes in each of the references. Therefore, there is no evidence presented to prove that the electrode of Ohara et al., is equivalent in all respects to the electrode of Gregg et al.

Conclusion

- 11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wilson, U.S. Pat. No. 5,211,984, teaches a tertbutyl ammonium modified perfluorosulfonic acid (col. 7, lines 10-20) in a fuel cell system.
- 12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela J. Martin whose telephone number is 571-272-1288. The examiner can normally be reached on Monday-Friday from 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Ryan can be reached on 571-272-1292. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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AJM

PATRICK JOSEPH RYAN
....COMY PATENT EXAMINER